



UNITED STATES PATENT AND TRADEMARK OFFICE

T.

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,372	07/24/2003	Harrihar A. Pershadsingh	421842000400	2447
25226	7590	05/05/2006		
MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018				
EXAMINER WEDDINGTON, KEVIN E				
ART UNIT			PAPER NUMBER	
1614				

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/627,372

Applicant(s)

PERSHADSINGH, HARRIHAR A.

Examiner

Kevin E. Weddington

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9, 10, 12, 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 10, 12, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1614

Claims 1-7, 9, 10, 12, 14 and 15 are presented for examination.

Applicants' amendment filed January 31, 2006 has been received and entered.

The applicants may wish to delete the word "prophylactically" in claims 1, 2, 4 and 7 since the words "inhibiting and inhibits" achieves the same effect.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9, 11 and 12 are again rejected under 35 U.S.C. 102(b) as being anticipated by Asmar et al., American Journal of Hypertension, Vol. 14, No. 4, pp. 114A, 2001, abstract P-254 of PTO-1449, all of record, for reason of record as set forth in the previous Office action dated January 3, 2006 at pages 2-3 as applied to claims 1-7, 9, 11 and 12.

Applicants' remarks regarding the prior art, Asmar et al., does not teach inherency to metabolic syndrome are not persuasive since the Examiner is trying to say the cited prior art, Asmar et al, teaches the instant active ingredient, telmisartan, is well- known to treat Type 2 diabetes and its complication such as hypertension. Note in applicants' specification, page 9, section [0023]; discloses the metabolic disorder or disease that can be treated with telmisartan such as the metabolic hypertensive syndrome wherein hypertension is present. Again, the cited reference anticipates the applicants' instant invention.

Art Unit: 1614

The rejection made under 35 USC 102(b) is adhered to.

Claims 1-7, 9, 11 and 12 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10, 14 and 15 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Asmar et al., American Journal of Hypertension, Vol. 14, No. 4, pp. 114A, 2001, abstract P-254 of PTO-1449, all of record, for reason of record as set forth in the previous Office action dated January 3, 2006 at pages 3-5 as applied to claims 10, 14 and 15.

Applicants' remarks regarding the prior art, Asmar et al., topical administration of telmisartan or a total daily effective oral dose is obvious over the allege inherent anticipation of the administration of telmisartan to patients with metabolic syndrome are not persuasive since the applicants' specification teaches one of the metabolic disorders is the metabolic hypertensive syndrome then the cited reference does anticipates the instant invention as states above supra.

As the topical administration of telmisartan, applicants have not demonstrated on the record how effective the topical administration in treating metabolic disorders of type 2 diabetes. Again, the Asmar et al. reference's dosage of 40 mg falls within

Art Unit: 1614

the applicants' dosage range of claim 12. Again, the various dose ranges of claim 14 is obvious since the body sizes of the human child, adolescent and adult are different thus various doses are needed for each individual group.

The rejection made under 35 USC 103 is adhered to.

Claims 10, 14 and 15 are not allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

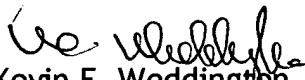
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 12:00 am-8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax

Art Unit: 1614

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
May 1, 2006